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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,)
)
Plaintiff,)
)
v.)
)
ACTAVIS TOTOWA, LLC,)
ACTAVIS, INC.,)
corporations, and)
SIGURDUR OLI OLAFSSON, and)
DOUGLAS BOOTHE,)
individuals,)
)
Defendants.)

Hon. Susan D. Wigenton

Civil Action No. 08-cv-05656

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction ("Complaint") against Actavis Totowa, LLC ("Actavis Totowa"), a limited liability company currently operating drug manufacturing facilities at 101 East Main Street, Little Falls, New Jersey; 990 Riverview Drive, Totowa, New Jersey; and 4 Taft Road, Totowa, New Jersey; and Actavis, Inc. (aka Actavis US), the direct parent of Actavis Totowa; and Sigurdur Oli Olafsson, and Douglas Boothe (who assumed his position as President and Chief Executive Officer of Actavis Totowa in August 2008), individuals (hereinafter, collectively, "Defendants"), alleging the following violations: (1) 21 U.S.C. § 331(a) – introducing and causing to be introduced, and delivering and causing to be delivered for introduction into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1) (hereinafter, "drug" or "drugs"), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that they have been manufactured, processed, packed, labeled, held, and distributed in violation of the current good manufacturing practice ("CGMP") requirements, 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211; (2) 21 U.S.C. § 331(k) – causing the adulteration within the meaning of 21 U.S.C. § 351(a)(2)(B) of articles of drug after shipment of one or more of their components in interstate commerce; (3) 21

U.S.C. § 331(a) – introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of drug that are misbranded under 21 U.S.C. § 352(f)(1), in that their labeling fails to bear adequate directions for use; (4) 21 U.S.C. § 331(k) – causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1); and (5) 21 U.S.C. § 331(d) – introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i); and Defendants, while denying the allegations in the Complaint and disclaiming any liability in connection therewith, have appeared and consented to entry of this Decree without contest and before any testimony has been taken, solely for the purpose of settling this case, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. § 332.

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (the "Act").

3. For purposes of this Decree, the following definitions shall apply:

A. "Actavis Totowa Facilities" shall refer to the facilities located at 101 East Main Street, Little Falls, New Jersey; 990 Riverview Drive, Totowa, New Jersey; and 4 Taft Road, Totowa, New Jersey;

B. "Oxycodone IR Drugs" shall refer to Oxycodone Immediate Release Tablets in 15 and 30 mg dosage strengths (ANDA No. 76-636);

C. "Other Oxycodone Drugs" shall refer to oxycodone-containing drug products, not including the Oxycodone IR Drugs defined in subparagraph B above, in various dosage strengths, including Oxycodone Immediate Release Tablets in 5 mg strength and the drugs that are the subject of ANDA Nos. 40-799, 40-800, 40-801, and 78-507. Defendants may elect to move one or more drug product from this category into the category defined in paragraph 3(D) by notifying the United States Food and Drug Administration ("FDA") in writing; however, the batch certification requirements set forth in paragraph 8(B) shall continue to apply to such drugs notwithstanding such move;

D. "All Other Drugs" shall refer to all articles of drug, not including the Oxycodone IR and Other Oxycodone Drugs defined in

subparagraphs B and C above, that Defendants manufacture at the Actavis Totowa Facilities.

4. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from, directly or indirectly manufacturing, processing, packing, labeling, holding, or distributing, or introducing or delivering for introduction into interstate commerce at or from the Actavis Totowa Facilities: (a) the Oxycodone IR Drugs; (b) the Other Oxycodone Drugs; and (c) All Other Drugs, unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute the Oxycodone IR Drugs, the Other Oxycodone Drugs, or All Other Drugs, as applicable, at the Actavis Totowa Facilities are established, operated, and administered in compliance with CGMP. 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211;

B. Defendants establish and document management control over Quality Assurance ("QA") and Quality Control ("QC") for the Actavis Totowa Facilities. Responsibility for QA and QC shall be vested in an individual who shall

be authorized and responsible for all QA and QC functions at the Actavis Totowa Facilities, including ensuring the establishment, implementation, and maintenance of a comprehensive quality assurance and quality control program ("QA/QC program") as described in subparagraph 4(D)(2) of this Decree, and facilitating ongoing compliance with the applicable provisions of this Decree. This individual shall also be responsible for ensuring that specific QA and QC responsibilities are assigned to appropriate and qualified personnel at the Actavis Totowa Facilities;

C. Defendants retain, at Defendant Actavis Totowa's expense, an independent person(s) (the "CGMP Expert"), who (i) is without any personal or financial ties (other than a retention agreement to satisfy the requirements of this provision, or retention agreements entered into prior to the entry of this Decree) to Defendants or their families, and (ii) by reason of background, training, education, or experience, is qualified to inspect the Actavis Totowa Facilities to determine whether the methods, facilities, and controls are operated and administered in conformity with CGMP. Defendants shall notify FDA in writing of the identity and qualifications of any current or future CGMP Expert within fifteen (15) calendar days of entry of this Decree or of retaining any such CGMP Expert;

D. The CGMP Expert reviews all Forms FDA-483 issued to Defendants since 2005 and performs a comprehensive inspection of the Actavis

Totowa Facilities and the methods and controls used to manufacture, process, pack, label, hold, and distribute the Oxycodone IR Drugs, the Other Oxycodone Drugs, or All Other Drugs at or from the Actavis Totowa Facilities, as applicable, to determine whether they are in compliance with CGMP. At a minimum, the CGMP Expert shall do the following:

(1) Evaluate whether the Defendants have established a comprehensive written QA/QC program that is adequate to ensure continuous compliance with applicable laws and regulations; and

(2) Determine whether the QA/QC program, at a minimum:

a. Addresses all facets of compliance monitoring and trend analyses, and internal audit procedures, and confirms that Defendants' Quality Control Unit, as defined by 21 C.F.R. § 210.3(b)(15), is adequately trained and staffed to evaluate CGMP compliance on an on-going basis and prevent and correct future deviations from CGMP;

b. Includes procedures to ensure that the Defendants, in a timely manner, thoroughly investigate any unexplained discrepancy or the failure of a batch of drug or its components to meet any of the product's or component's specifications, including the extension of such investigation to other batches of the same drug product and other drug products that may have been

associated with the specific failure or discrepancy, and to take required and timely corrective actions for all products that fail to meet their specifications;

c. Includes procedures to ensure that the Defendants, in a timely manner, thoroughly investigate any complaints or returns, and any associated trends, and take any needed corrective actions in a timely manner;

d. Establishes mechanisms to ensure that written standard operating procedures (SOPs) are periodically evaluated to ensure they reflect current and CGMP-compliant practices, and that these SOPs provide for all facets of CGMP compliance to be reviewed and controlled by an independent QA unit; and

e. Includes written SOPs to ensure that the Defendants' QA personnel participate in or monitor the implementation and verification of corrective actions to prevent future occurrences of such deviations and/or problems and that there are systems to ensure that such written SOPs are continuously followed;

E. The CGMP Expert certifies in writing to FDA and Defendants the following:

(1) With respect to the Oxycodone IR Drugs, that he or she has inspected the facilities, methods, processes, and controls that are generally

applicable to the production of any and all drug products at the Actavis Totowa Facilities ("general systems"), and the specific methods, processes, and controls applicable to the Oxycodone IR Drugs, and that: (i) all CGMP deviations at the Actavis Totowa Facilities applicable to the general systems and the Oxycodone IR Drugs have been corrected; (ii) the general systems and the specific methods, processes, and controls applicable to the Oxycodone IR Drugs are in compliance with CGMP; and (iii) the Oxycodone IR Drugs have approved ANDAs. As part of this certification, the CGMP Expert shall include a full and complete detailed report of the results of his or her inspection.

(2) With respect to the Other Oxycodone Drugs, that he or she has inspected the Actavis Totowa Facilities, including the general systems and the specific methods, processes, and controls applicable to the Other Oxycodone Drugs, and that: (i) all CGMP deviations at the Actavis Totowa Facilities applicable to the general systems and the Other Oxycodone Drugs have been corrected; (ii) the general systems and the specific methods, processes, and controls applicable to the Other Oxycodone Drugs are in compliance with CGMP; and (iii) the Other Oxycodone Drugs have ANDAs or ANDA supplements pending FDA approval. As part of this certification, the CGMP Expert shall include a full and complete detailed report of the results of his or her inspection. Within thirty

(30) calendar days of receiving the CGMP Expert's certification with respect to the Other Oxycodone Drugs, but only if Defendants' ANDAs for the Other Oxycodone Drugs are otherwise approvable, FDA representatives shall inspect the Actavis Totowa Facilities to determine whether, with respect to the Other Oxycodone Drugs, they are operating in conformity with CGMP, the Act, and its implementing regulations, to determine whether Defendants' Other Oxycodone Drugs can be approved.

(3) With respect to All Other Drugs, that he or she has inspected the Actavis Totowa Facilities, including the general systems and the specific methods, processes, and controls applicable to All Other Drugs, and that:

(i) all CGMP deviations at the Actavis Totowa Facilities applicable to the general systems and All Other Drugs have been corrected; (ii) the general systems and the specific methods, processes, and controls applicable to All Other Drugs are in compliance with CGMP; and (iii) All Other Drugs have approved ANDAs, or have ANDAs or ANDA supplements pending FDA approval. As part of this certification, the CGMP Expert shall include a full and complete detailed report of the results of his or her inspection.

Once the CGMP Expert certifies to FDA in writing under this paragraph that the general systems are in compliance with CGMP, and FDA has confirmed by

inspection that the general systems are in compliance with CGMP, the CGMP Expert shall not be required to conduct additional inspections or provide additional certifications with respect to the general systems under this paragraph, unless any intervening audit inspection conducted pursuant to paragraph 8(C) of this Decree or any FDA inspection finds that Defendants have failed to maintain CGMP compliance for the general systems.

F. Defendants report to FDA in writing as to the Oxycodone IR Drugs, the Other Oxycodone Drugs, and/or All Other Drugs, as applicable, the actions they have taken to do the following:

(1) Correct all CGMP deviations applicable to the general systems and the CGMP deviations specifically related to the Oxycodone IR Drugs, the Other Oxycodone Drugs, and/or All Other Drugs, as applicable. Once Defendants have reported to FDA in writing under this paragraph the actions they have taken to correct the deviations applicable to the general systems, and FDA has confirmed by inspection that the general systems are in compliance with CGMP, Defendants shall not be required to provide additional reports with respect to the general systems under paragraph 4(F), unless any intervening audit inspection conducted pursuant to paragraph 8 of this Decree or any FDA inspection finds that Defendants have failed to maintain CGMP compliance for the general systems;

(2) Ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing the drugs are operated and administered, and will be continuously operated and administered, in conformity with CGMP; and

(3) Ensure that all drug products manufactured, processed, packed, labeled, held, or distributed at or from the Actavis Totowa Facilities have an approved new drug application or abbreviated new drug application under 21 U.S.C. § 355 (unless the drug is exempt from the approval requirements pursuant to an effective exemption under 21 U.S.C. § 355(i)), and that such drugs have adequate directions for use, as required by 21 U.S.C. § 352(f)(1).

Defendants may choose to provide separate reports to FDA for the Oxycodone IR Drugs, the Other Oxycodone Drugs, and All Other Drugs for purposes of complying with this paragraph. However, if Defendants fail to submit the required reports under this paragraph for one or more of the categories of drugs defined in paragraph 3(B)-(D) of this Decree within twenty-four (24) months after the entry of this Decree, such failure shall constitute Defendants' abandonment of any intention to resume manufacture at the Actavis Totowa Facilities of one or more of the drug products falling within such category of drugs. At any time after entry of this Decree, the Defendants may choose to abandon their intention to

resume or commence the manufacture of one or more drug products falling within the categories of drugs defined in paragraph 3(B)-(D) by notifying FDA in writing. Any such abandonment shall apply only to those drug product(s) that are the subject of such notice(s) and shall not be deemed to be abandonment of the entire category of drugs defined in paragraphs 3(B)-(D).

G. Within thirty (30) calendar days of receipt of Defendants' report(s) for the Oxycodone IR Drugs, Other Oxycodone Drugs, or All Other Drugs under paragraph 4(F), as applicable, FDA may, in its discretion and without prior notice, commence an inspection of the Actavis Totowa Facilities to determine whether the applicable Actavis Totowa Facilities are operating in conformity with CGMP, the Act, its implementing regulations, and this Decree. If FDA determines, through an inspection of the Actavis Totowa Facilities, or otherwise, that the Defendants are not operating in conformity with CGMP, the Act, its implementing regulations, and this Decree, FDA will notify the Defendants of the deficiencies it observed and will take such other action, if any, as the Agency deems appropriate (e.g., issuing an order pursuant to paragraph 16). Within thirty (30) calendar days of receiving a deficiency notification from FDA under this paragraph, Defendants shall submit to FDA a plan of actions that Defendants propose to take and a proposed timetable for correcting the deficiencies. The plan and timetable shall be

subject to FDA approval. Defendants shall promptly correct all deficiencies noted by FDA in accordance with the FDA-approved timetable, and shall cause the CGMP Expert to reinspect and either (i) certify that the deficiencies have been corrected, or (ii) notify Defendants that one or more deficiencies remain uncorrected. If one or more deficiencies have not been corrected, the CGMP Expert shall notify the Defendants of the remaining deficiencies and the actions by the Defendants needed to address those deficiencies. The Defendants are required to take the steps necessary to resolve any such remaining deficiencies until the CGMP Expert is satisfied and issues the certification. The Defendants shall then submit the certification to FDA. Within forty-five (45) calendar days of FDA's receipt of the certification, FDA may reinspect as it deems necessary; and

H. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 4(A)-(G). If Defendants have satisfied the criteria under paragraphs 4(A)-(G) to resume operations with respect to one or more of the Oxycodone IR Drugs, the Other Oxycodone Drugs, or All Other Drugs, but not all such drug products, as and when FDA deems appropriate, FDA may issue the notice under this paragraph and authorize a partial resumption of manufacture and distribution for a specific product(s). If FDA decides to commence an inspection pursuant to paragraph

4(G), FDA will determine whether to provide this notification within forty-five (45) calendar days of concluding that inspection, and notify Defendants of its determination. If FDA decides not to commence an inspection pursuant to paragraph 4(G), FDA will determine whether to provide this notification within forty-five (45) calendar days of FDA's receipt of each report submitted by the Defendants under paragraph 4(F), and notify Defendants of its determination. In no circumstance will FDA's silence be construed as a substitute for written notification.

I. Except as provided for in paragraph 5 below, Defendants may not manufacture, process, pack, hold, or distribute the drugs that are the subject of ANDA Nos. 40-799, 40-800, 40-801, and 78-507 at or from the Actavis Totowa Facilities until Defendant Actavis Totowa receives FDA approval of an ANDA or ANDA supplement for such drug.

5. Paragraph 4 shall not apply to the activities described in subparagraphs 5(A) - (E) below. None of the drugs produced under subparagraphs 5(B) - (E) below at the Actavis Totowa Facilities may be distributed without prior written authorization from FDA.

A. Distributing any FDA-approved drug products manufactured, processed, packed, labeled, held, or distributed at or by third parties, so long as

Defendant Actavis Totowa performs no manufacturing, processing, packing, or labeling functions with respect to the drugs, and its sole responsibility is that of a distributor;

B. Manufacturing, processing, packing, holding, and distributing drug products for the purpose of performing equipment qualification, validation of drug manufacturing processes, or conducting method validation or stability studies. Defendants shall maintain in a separate file at the Actavis Totowa Facilities a written log of all lot numbers of drugs manufactured under this provision, and shall promptly make such log available to FDA upon request;

C. Manufacturing, processing, packing, and holding quantities of products necessary for preparing or supporting a new drug application or an abbreviated new drug application;

D. Manufacturing, processing, packing, holding, or distributing products for non-clinical laboratory studies or other research and testing that does not involve exposure of human research subjects; and

E. Manufacturing, processing, packing, holding, or distributing a drug product in accordance with a written request by Defendants to FDA, provided that: (i) Defendants have submitted to FDA all documentation and justification for

such request that FDA deems necessary; and (ii) FDA has authorized Defendants in writing to perform such activity with respect to such drug.

6. Upon entry of this Decree, Defendants Actavis Totowa and Actavis, Inc., and Defendants Sigurdur Oli Olafsson and Douglas Boothe, for so long as they, respectively, are in positions of responsibility with Defendants Actavis Totowa or Actavis, Inc., or any of Defendant Actavis Totowa's or Defendant Actavis, Inc.'s franchisees, subsidiaries, affiliates, or "doing business as entities," and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons or entities in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Introducing or delivering for introduction into interstate commerce any drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

B. Causing the adulteration of any drug within the meaning of 21 U.S.C. § 351(a)(2)(B), while such drug is held for sale after shipment of one or more components in interstate commerce;

C. Introducing or delivering for introduction into interstate commerce any drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1);

D. Causing the misbranding of any drug within the meaning of 21 U.S.C. § 352(f)(1), while such drug is held for sale after shipment of one or more components in interstate commerce; and

E. Introducing or delivering for introduction into interstate commerce any new drug that is not the subject of an approved application under 21 U.S.C. § 355(a) or is not the subject of an investigational new drug application under 21 U.S.C. § 355(i).

7. Except as provided in this paragraph, within fifteen (15) calendar days of entry of this Decree, Defendants shall, under FDA supervision, destroy all drugs in Defendants' possession, custody, and/or control that are the subject of recalls announced by Actavis US in April, May, June, and July 2008. With respect to any additional recalled drug products that subsequently come into the Defendants' possession, custody, or control, the Defendants shall quarantine any such products, notify FDA of their receipt, and destroy any such products, under FDA's supervision, no later than thirty (30) calendar days after their receipt. Recalled drug products that are the subject of pending or threatened litigation, however, may

be preserved for evidentiary purposes only, for so long as that need exists, but shall be destroyed, under FDA's supervision when that need no longer exists. Within thirty (30) calendar days of receipt of a reasonable detailed bill of costs, Defendant Actavis Totowa shall reimburse FDA for the supervision of any destruction under this paragraph, and for FDA's supervision of Defendants' destruction of products since March 18, 2008, and prior to entry of this Decree, at the rates set forth in paragraph 11 of this Decree. Defendants shall not dispose of any drugs in a manner contrary to any federal, state, or local laws, including but not limited to, the National Environmental Policy Act of 1969.

8. Once FDA first notifies Defendants pursuant to paragraph 4(H) that they may resume operations with respect to any category of drugs defined in paragraph 3(B)-(C) of this Decree, Defendants shall retain an independent person(s) who meets the criteria described in paragraph 4(C) (hereinafter, "Auditor") and who may, if Defendants choose, be the same person(s) retained as the CGMP Expert in paragraph 4(C), to conduct batch certifications of drugs manufactured at the Actavis Totowa Facilities and audit inspections of the drug manufacturing and packaging operations at the Actavis Totowa Facilities.

A. The Auditor shall submit to FDA for approval a written batch certification protocol ("certification protocol"), and shall not commence batch certification until FDA has approved the certification protocol in writing.

B. For the Oxycodone IR and Other Oxycodone Drugs, Defendants shall obtain from the Auditor or CGMP Expert a written certification that he or she has witnessed the manufacture of three (3) consecutive batches of each drug in these categories and examined the manufacturing and control records, and the raw data associated with such records for each drug, in accordance with the FDA-approved certification protocol, and determined that each batch has the identity, strength, quality, and purity it purports and is represented to possess, and submit such certifications, signed by the Auditor and/or CGMP Expert and a responsible company employee who has also reviewed the manufacturing records, to FDA prior to release of the finished product. After the Auditor and/or CGMP Expert certifies three (3) consecutive batches of each drug in the Oxycodone IR Drugs category and the first three (3) consecutive batches of each drug in the Other Oxycodone Drugs category as set forth above, the Auditor and/or CGMP expert may certify all additional batches required to be certified under the FDA-approved certification protocol based only on an examination of the manufacturing and control records, and raw data associated with such records, in accordance with the

FDA-approved certification protocol. For the Oxycodone IR Drugs, this additional third-party batch certification shall be performed in accordance with the FDA-approved certification protocol until twelve (12) additional consecutive batches are manufactured and certified, and for an additional period of one (1) year thereafter, the Auditor shall certify one (1) batch of each strength of the Oxycodone IR Drugs every three months. For the Other Oxycodone Drugs, this additional third-party batch certification shall be performed in accordance with the FDA-approved certification protocol until twelve (12) consecutive batches of each drug are manufactured and certified, or for a period of one (1) year, whichever comes first.

If the Auditor determines that a batch of drug failed to have the identity, strength, quality, and purity it purports and is represented to possess, and such failure was due solely to a non-process related issue, the Auditor may provide to FDA a written explanation for the batch failure and all relevant supporting data. If, in FDA's discretion, the agency agrees that the batch failure was due solely to a non-process related issue, FDA will advise Defendants in writing that the failed batch will not interrupt the continuously compliant findings for such drug and the Auditor need not begin the series of batch certifications for such drug anew. FDA's decision shall be final.

C. For each category of drugs defined in paragraph 3(B)-(D), once Defendants have obtained written authorization under paragraph 4(H) from FDA to resume or commence the manufacture of such category of drugs, the Auditor shall conduct audit inspections of Defendants' manufacturing and packaging operations with respect to such category of drugs no less frequently than once every six (6) months for a period of no less than three (3) years, and annually thereafter for no less than two (2) additional years, for a total of five (5) years.

9. At the conclusion of each audit inspection required by paragraph 8(C) of this Decree,

A. The Auditor shall prepare a detailed written audit report ("audit report") analyzing whether Defendants are in compliance with CGMP and identifying any deviations from CGMP ("audit report observations" or "observations"). As a part of every audit report, except the first audit report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. Each audit report shall be delivered simultaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) business days after the date the audit inspection(s) is completed. In addition, Defendants shall maintain the audit reports in separate

files at the Actavis Totowa facility located in Little Falls, New Jersey, and shall promptly make the audit reports available to FDA upon request; and

B. If an audit report contains any observations that the Actavis Totowa Facilities are not in compliance with CGMP, Defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the deviation(s) will take longer than thirty (30) calendar days, Defendants shall, within ten (10) calendar days of receipt of the audit report, submit to FDA in writing a proposed schedule for completing corrections ("correction schedule"). The correction schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance will FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days of Defendants' receipt of an audit report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days of beginning that review, the Auditor shall report in writing to

FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected.

10. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the Actavis Totowa Facilities and take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted ready access to the Actavis Totowa Facilities including, but not limited to, all buildings, equipment, finished and unfinished materials and products, containers and packaging material therein, labeling, and other promotional material therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers and packaging material therein, labeling, and other promotional material; and to examine and copy all records relating to the manufacture, processing, packing, labeling, receiving, holding, and distribution of any and all of Defendants' drugs, including components, in order to ensure continuing compliance with the terms of this Decree. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374. FDA will

provide Defendants with a receipt for any samples taken pursuant to this paragraph or 21 U.S.C. § 374, and with copies of any photographs or video recordings made after receipt of a written request by Defendants for such copies, and at the Defendants' expense.

11. Defendant Actavis Totowa shall reimburse FDA for all costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews relating to the Actavis Totowa Facilities that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree at the standard rates prevailing at the time the activities are accomplished. As of the date of entry of this Decree, these rates are: \$81.61 per hour or fraction thereof per representative for inspection and investigative work; \$97.81 per hour or fraction thereof per representative for laboratory and analytical work; \$0.585 per mile for travel expenses by automobile, government rate or the equivalent for travel by air; and the published government per diem rate for subsistence expenses where necessary. FDA shall submit a reasonably detailed bill of costs to Defendant Actavis Totowa at the address specified in paragraph 24. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased accordingly without further order of the Court. In addition, should Plaintiff bring, and prevail in, a contempt action to

enforce the terms of this Decree, Defendant Actavis Totowa shall pay all attorneys' fees and costs, travel expenses incurred by attorneys and witnesses, expert witness fees, investigational and analytical expenses, and court costs incurred by Plaintiff in bringing such an action.

12. Within ten (10) calendar days of the entry of this Decree, Defendants shall post a copy of this Decree on a bulletin board in a common area at the Actavis Totowa Facilities and at any other location at which Defendants conduct business in the United States, and shall ensure that the Decree remains posted at such locations for as long as the Decree remains in effect.

13. Within ten (10) calendar days of the date of entry of this Decree, Defendants shall provide a copy of the Decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of the following "Associated Persons": (i) employees, directors, officers, agents, representatives, attorneys, and assigns of Actavis Totowa, and any and all persons or entities in active concert or participation with any of them, including, but not limited to, the Vice President Quality and Compliance of Actavis Group; and (ii) all parties for whom Actavis Totowa contract manufactures drugs and own label distributors with whom Actavis Totowa is affiliated, and all others involved in the manufacture or quality of Actavis Totowa's drug products. Within twenty (20) calendar days of

the date of entry of this Decree, Defendants shall ensure that all other employees involved in the manufacture, storage, or distribution of drugs at the Actavis Totowa Facilities are aware of the terms of this Decree by providing them with copies or by posting copies in conspicuous places frequented by and readily available to employees. Within thirty (30) calendar days of the date of entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who or entities which received a copy of this Decree pursuant to this paragraph.

14. In the event that, any time after entry of this Decree, any of the Defendants become associated with any additional Associated Person(s), Defendants shall, within ten (10) business days of the commencement of such association, provide a copy of this Decree to such additional Associated Person(s), by personal service or certified mail (restricted delivery, return receipt requested) and, on a quarterly basis, notify FDA in writing, in accordance with paragraph 24, when, how, and to whom the Decree was provided. Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons or entities who received a copy of this Decree pursuant to this paragraph, and attaching a

copy of the executed certified mail return receipts. Within ten (10) calendar days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

15. Defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, character, or name of any of Defendant Actavis Totowa's drug manufacturing businesses, including incorporation, reorganization, bankruptcy, assignment, sale resulting in the emergence of a successor business or corporation, or any other change in the structure or identity of Actavis Totowa (or any of its parents or subsidiaries), or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect any obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least ten (10) calendar days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

16. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report or data prepared or submitted by Defendants, the CGMP Expert, the Auditor, or any other information,

that, with respect to the Actavis Totowa Facilities, Defendants have failed to comply with any provision of this Decree, have violated CGMP, the Act, or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, CGMP, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action with respect to the Actavis Totowa Facilities, including, but not limited to, ordering Defendants to immediately take one or more of the following actions with respect to the Actavis Totowa Facilities:

- A. Cease all manufacturing, processing, packing, labeling, holding, and/or distributing any or all drug(s);
- B. Recall, at Defendant Actavis Totowa's expense, any drug that is adulterated, misbranded or otherwise in violation of this Decree, CGMP, the Act, or its implementing regulations;
- C. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;
- D. Submit additional reports or information to FDA;
- E. Issue a safety alert; and/or

F. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or to bring Defendants into compliance with this Decree, CGMP, the Act, or its implementing regulations.

Any FDA order issued pursuant to this paragraph shall specify the noncompliances giving rise to the order.

17. The following process and procedures shall apply when FDA issues an order under paragraph 16, except as provided in subparagraph (D) below:

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving such order, Defendants shall notify FDA in writing either that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants also shall describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as the Agency deems appropriate. If FDA affirms

or modifies its order, it shall explain the basis for its decision in writing. The written notice of affirmance or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and if they so choose, bring the matter before this Court on an expedited basis. Defendants shall continue to diligently implement FDA's order, unless the Court sets aside, stays, reverses, vacates, or modifies FDA's order. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in paragraph 23 of this Decree.

D. The process and procedures set forth in paragraph 17(A)-(C) shall not apply to any order issued pursuant to paragraph 16 if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, the Defendants shall immediately and fully comply with the terms of that order. Should the Defendants seek to challenge any such order, they may petition this Court for relief.

18. Any cessation of operations or other action described in paragraphs 16-17 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, CGMP, the Act, and its implementing regulations, and that Defendants may, therefore, resume operations.

Upon Defendants' written request to resume operations, FDA shall endeavor to determine within forty-five (45) calendar days of receipt of the request whether Defendants appear to be in compliance and, if so, issue to Defendants without delay written notification permitting resumption of operations. Defendant Actavis Totowa shall pay all costs of such recalls and corrective actions, including the costs of FDA supervision, inspections, investigations, analyses, examinations, reviews, travel, and subsistence expenses to implement recalls and other corrective actions, at the rates specified in paragraph 11 of this Decree. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

19. The parties may at any time petition each other in writing to extend any deadline provided for herein, and such extension may be granted without seeking leave of Court. However, any such petitions by Actavis Totowa shall not become effective or stay the imposition of any payments under this Decree unless granted by FDA in writing.

20. Defendant Sigurdur Oli Olafsson and/or Defendant Douglas Boothe shall notify FDA if, at any time after entry of this Decree, he ceases to be employed by or affiliated in any way with Defendants Actavis Totowa and Actavis, Inc. Such individual Defendant may, after providing FDA thirty (30) calendar days written notice, petition the Court to be released from this Decree.

Unless, within such 30-day period, FDA determines that Mr. Olafsson or Mr. Boothe, as applicable, has not ceased to be employed by or affiliated with Defendants Actavis Totowa and/or Actavis, Inc., FDA will not oppose release of such individual from this Decree pursuant to such petition.

21. If Defendants fail to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then Defendant Actavis Totowa shall pay to the United States of America: fifteen thousand dollars (\$15,000) in liquidated damages for each day such violation continues, and an additional sum of fifteen thousand dollars (\$15,000) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree. The amount of liquidated damages imposed under this paragraph shall not exceed seven million dollars (\$7,000,000) in any one calendar year. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, or the power of the Court to impose, additional criminal or civil penalties or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

22. If Defendants fail to comply with any of the provisions of this Decree or such further order as may be entered in this proceeding, and are found in civil or

criminal contempt thereof, Defendant Actavis Totowa shall, in addition to other remedies, reimburse the United States for its attorneys' fees, all investigational expenses, and court costs relating to such violation and contempt proceedings.

23. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

24. Unless FDA notifies the Defendants otherwise in writing, all notifications, correspondence, and communications to FDA required by the terms of this Decree shall be addressed to the District Director, FDA New Jersey District Office, 10 Waterview Boulevard, Third Floor, Parsippany, New Jersey, 07054. All notifications, correspondence, and communications required to be sent to Defendants under this Decree shall be addressed to Vice President of Quality, Actavis, Inc., 60 Columbia Road, Building B, Morristown, New Jersey, 07960.

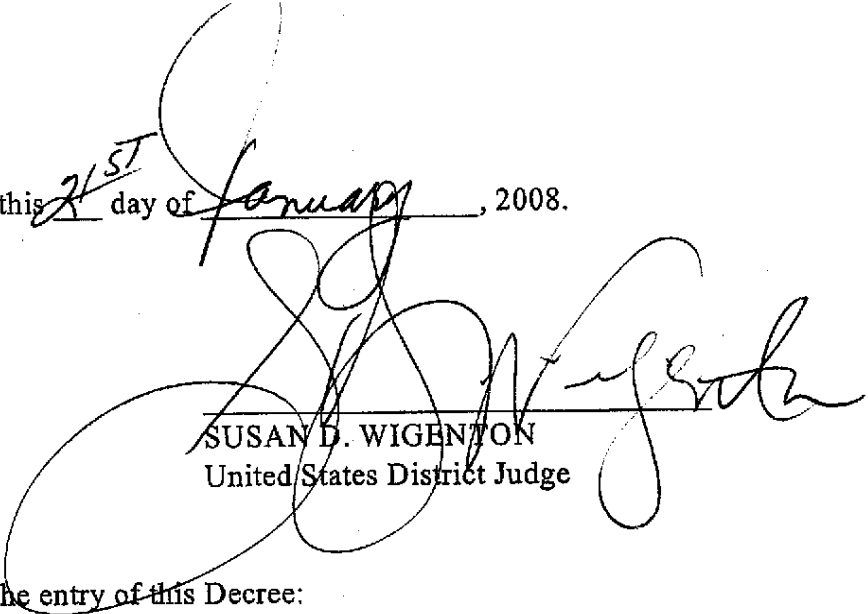
25. If Defendants have maintained at the Actavis Totowa Facilities a state of continuous compliance with this Decree, the Act, and all applicable regulations

for all of the drugs in the categories defined in paragraphs 3(B)-(D) for at least sixty (60) months after satisfying all of their obligations under paragraph 4, Defendants may petition this Court for relief from this Decree and Plaintiff will not oppose such petition.

26. Should Defendants at any time seek, through the filing of a supplemental application or amendment, to change the manufacturing site listed in an approved application or pending application from the Actavis Totowa Facilities to a manufacturing site other than the Actavis Totowa Facilities, or to transfer ownership rights of approved or pending applications, so long as the action is otherwise in accordance with all applicable statutory and regulatory provisions including, but not limited to, 21 U.S.C. §§ 355, 356a; 21 C.F.R. § 314.70, and any and all applicable binding guidances regarding changes to approved drug applications, nothing in this Decree shall be read to prevent the authorization of such a manufacturing site change or transfer of ownership rights of approved or pending applications.

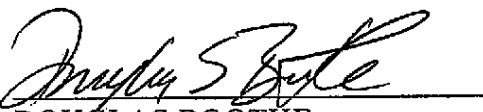
27. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

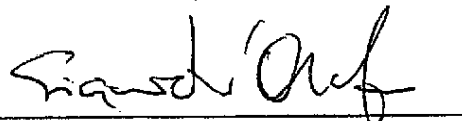
SO ORDERED, this 21ST day of January, 2008.



SUSAN D. WIGENTON
United States District Judge

We hereby consent to the entry of this Decree:

For Defendants:


DOUGLAS BOOTHE
Individually and on behalf
of ACTAVIS TOTOWA, LLC,
and ACTAVIS, INC.



SIGURDUR OLI OLAFSSON
Individually



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